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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/430,050
Filing Date: October 29, 1999
Appellant(s): CHU ET AL.

David Crompton
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 27, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-9, 11-15 and 21 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

6,083,207	Heck	7-2000

(10) Grounds of Rejection

Claims 1-9, 11-15 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Heck, 6,083,207. Heck discloses means (212) for breaking said valve body along a predetermined location; means (70, 71) for coupling said valve body to a peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen; means (50) for receiving a compressible valve sleeve having a lumen therethrough for coupling said valve sleeve lumen to said valve body lumen; and means (52 and 56) for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through valve and valve sleeve lumen. A compressible valve sleeve is disclosed as a medical device, see column 5, lines 33-34, column 9, lines 18-19), wherein the proximal end of the valve sleeve extends proximal of said means for compressing said valve sleeve.

As to claim 2, the valve sleeve inherently includes a free end extending past said means for compressing, and further comprising means (206) for receiving a catheter tip within said valve sleeve lumen free end while said means for compressing is compressing said valve sleeve, such that said valve sleeve lumen is substantially occluded by said inserted catheter tip while said catheter tip is inserted.

As to claim 3, Heck discloses a means (52, 20 and 56) for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end; means (70, 71)

for breaking apart said fluid flow restricting means responsive to applied force; and means (50) for admitting a catheter distal end into said valve.

As to claim 4, the means (52, 20 and 56) for reversibly restricting flow has an open position for allowing flow therethrough and a closed position for substantially restricting flow, wherein said means (50) for admitting said catheter distal end includes means for admitting said catheter distal end while said means for restricting flow is in said closed position.

As to claim 5, said means (52, 20 and 56) for restricting flow includes a flexible, constrictable tube (20) having a lumen therethrough.

As to claim 6, said means (52, 20 and 56) for restricting flow includes means (52) for pinching said flexible tube for constricting said flexible tube lumen.

As to claim 7, said means for pinching has at least two portions (26, 28) movable with respect to each other, said two portions having means (52) for accepting and pinching said flexible tube therebetween, said two portions together having an open position and a closed position.

As to claim 8, said movable pinching member portions are hingedly coupled together with at least one hinge, see column 7, lines 33-36, and see Figure 3.

As to claim 9, said sheath has a longitudinal axis and said at least one hinge has an axis substantially parallel with said sheath longitudinal axis and said hinge enables movement of said pinching member portions about said hinge longitudinal axis for pinching said flexible tube in said closed position, see column 7, lines 33-36, and see Figure 3.

As to claim 11, when in said closed position, said pinching members (52 and 56) include means for leaving sufficient space in said flexible tube lumen for passage of a guide wire.

As to claim 12, Heck discloses a tubular, distal introducer sheath (20) having a proximal region and a lumen therethrough, said sheath having at least one longitudinal strip (212) for preferentially tearing said sheath along said strip, see column 9, lines 7-9; a tubular, flexible, proximal valve sleeve (medical device, see column 5, lines 33-34, column 9, lines 18-19) having a proximal region, a distal region, and a lumen therethrough; and a valve body (12) having a lumen therethrough and being sealingly coupled to said introducer sheath proximal region, said valve having at least one weakened region (near 94) for preferentially splitting said valve into at least two pieces responsive to an applied breaking force, said valve body having a seat (50) for mating to said proximal valve sleeve distal region, said valve body including a pinch member (52) for pinching said flexible valve sleeve and having a closed position for constricting fluid flow through said valve sleeve and an open position for admitting a catheter inserted through said valve sleeve.

As to claim 13, said flexible valve sleeve includes a free portion proximal of said pinch member for admitting said catheter into said sleeve free portion while said pinch member is in said closed position.

As to claim 14, said valve body pinch member (52) includes a recess therein for allowing passage of a guide wire through said pinch member while said pinch member is in said closed position.

As to claim 15, Heck discloses a breakaway distal portion (20) having a lumen therethrough for receiving said introducer sheath proximal region; and a proximal portion (12) including two opposed valve body members (26, 28), at least one of which is movable relative to the other and having concave surfaces therebetween for receiving a flexible valve sleeve therebetween, said valve body opposed members having an open position and a closed position, wherein said valve body members move apart relative to each other to reach said open position and said valve body opposed members move together relative to each other to reach said closed position, see column 7, lines 33-37, and column 8, lines 26-30) wherein said flexible sleeve has a lumen therethrough and said sleeve and sleeve lumen are constricted between said body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position.

As to claim 21, said valve body members (26, 28) are considered pivotally mounted to each other along at least one hinge oriented substantially parallel to said valve body lumen longitudinal axis, see column 7, lines 33-37, and column 8, lines 26-30.

As to claims 24 and 28, a sheath receiver is disclosed at (16). Moreover, when the compressible valve sleeve is received by the pinch member and the introducer sheath, fluid communication is created from the introducer sheath lumen into the compressible valve sleeve lumen.

As to claims 25, 26, 29 and 30, when the valve sleeve with a guidewire is received by the pinch member and the pinch member is in the closed configuration, fluid flow through the compressible valve sleeve is substantially prevented.

As to claims 27 and 31, a valve sleeve seat (see distal end of 13) for receiving a distal end of a compressible valve sleeve, wherein the valve sleeve seat is located between the pinch member and the sheath receiver.

(11) Response to Argument

On page 10 of the appeal brief Appellant disagrees with Examiner's position that the hemostasis valve of Heck compresses element (300). Appellant argues on page 11 that the Heck valve seals around element (300) rather than compressing it. Appellant states on page 11, lines 9-10, that:

'[b]ecause a hemostasis valve does not inherently or otherwise compress a device that is passed through the body of the valve, and Heck uses this standard definition, Heck does not disclose a valve that compresses "said valve sleeve for restricting fluid flow."'

Appellant has not pointed to any particular passage in Heck to support the assertion that a hemostatis valve does not inherently or otherwise compress a device that is passed through the body of the valve. Moreover, Examiner does not find any disclosure in Heck that supports that assertion, nor does Examiner find any disclosure in Heck that states that the Heck invention is a hemostasis valve that does not inherently or otherwise compress a device that is passed through the body of the valve. The most relevant disclosure in Heck on this point is in column 9, lines 31-34, which states:

"Because the hemostasis valve sections (38,40) are forced together, the partitioned hemostasis valve (14) acts like a conventional hemostasis valve, minimizing the amount of blood loss during the procedure."

However, this disclosure only states that the Heck valve acts like a conventional hemostasis valve in that it minimizes the amount of blood loss. It does not state or imply that the Heck valve does not compress a device that is passed through it.

Appellant also argues at the bottom of page 11 to page 12 that one skilled in the art would not compress a medical device such as a dilator or a catheter, since medical devices do not operate well if kinks or bends are put in them. Examiner reasserts however that the operation of the Heck device as described by Heck discloses that a catheter is compressed in the device. Heck discloses in column 6, lines 49-53 that a medical device is forced between the lips (56) (see figure 6), and that the medical device may be a catheter (column 5, lines 33-34), and that because the valve sections (38 and 40) are forced together, they minimize the amount of blood loss during a medical procedure (column 9, lines 30-33.) Thus, Examiner asserts that a catheter forced between the lips (56) when the valve sections (38 and 40) are forced together would be compressed.

Appellant also argues on page 12, in the first two full paragraphs that one skilled in the art would not use a medical device such as a catheter or dilator in place of the compressible valve sleeve. However, Examiner is not asserting that one skilled in the art would use a catheter in place of a compressible valve sleeve. Rather, the rejection is based on the catheter disclosed in Heck being considered the claimed compressible valve sleeve, since it meets the claims structurally and functionally.

Appellant also argues on page 12, last paragraph, that there is no structure in Heck that performs the function of compressing a valve sleeve. Examiner reasserts that lips (56) perform this function.

Appellant also argues on page 13 that the lips (56) are pliant and thus form a seal around a device as opposed to compressing a device. In support of this assertion, Appellant cites Heck, column 6, lines 44-46, which states that the valve sections provide "space for lips (56) to separate without excessive force being applied, as the medical device passes through the lips (56)." Appellant also points out that Heck also describes the outside wall sections as serving to "prevent the lips from opening when no pressure is placed on them" (Heck, column 6, lines 60-62.)

Examiner asserts that given the structure of the lips (56), (see Figure 6; see also Figures 10 and 3, disclosing the lips although not labeling the lips 56), and the function of the valve, a catheter placed between the lips (56) would be compressed between lips (56).

Appellant also argues on page 14 that while a catheter may be capable of being compressed to some degree, there is no teaching or suggestion in Heck that the valve would compress a catheter to the degree that fluid flow through it would be restricted. Examiner asserts that a catheter, having a lumen, would be compressed such that fluid flow through it would be restricted.

Appellant also argues on page 14, last paragraph, that Examiner's assertion that Heck teaches a hemostasis valve that compresses element (300) is contrary to the manner in which a hemostasis valve normally operates. Appellant further states on page 15 that Heck describes a valve that operates as a conventional hemostasis valve and that a conventional hemostasis valve does not create a seal by compressing a device but rather prevents flow around the exterior of a device inserted through the hemostasis valve. On page 16 of the brief, Appellant points out that Heck discloses in column 9, lines 31-32 that "the partitioned hemostasis valve (14) acts like a conventional hemostasis valve".

In response, Examiner points out that the full disclosure by Heck states that "the valve (14) acts like a conventional hemostasis valve, minimizing the amount of blood loss during the procedure." Thus, as mentioned before, the Heck valve acts like a conventional hemostasis valve in that it minimizes the amount of blood loss during a medical procedure. This passage in Heck does not suggest that the Heck valve does not compress a catheter inserted into it. Likewise, nowhere else in Heck is there a disclosure that the Heck valve or a conventional valve does not compress a catheter.

Also, Appellant on page 16 points out that Heck discloses that a pacemaker lead can also be received by the valve. Appellant asserts that since a pacemaker lead does not have a lumen, Heck cannot possibly be construed to have means for compressing a valve sleeve for restriction fluid flow through the valve sleeve lumen. Examiner however does not rely on a pacemaker lead being the claimed sleeve. Rather, Examiner refers to the catheter as being the sleeve.

At the bottom of page 16 to top of page 17 in the brief, Appellant also cites Heck as disclosing that it is not desirable for a physician to squeeze or pinch a sheath between his thumb and forefinger because squeezing the sheath can deform or even break the sheath. Appellant, on page 17, relies on this disclosure by Heck to indicate that a device being passed through the valve should not be compressed or squeezed. Examiner however emphasizes that Heck is referring to the squeezing of a sheath between the fingers of a user. This disclosure does not mean that the Heck valve does not operate by compressing a catheter placed in the valve.

Appellant also emphasizes on page 17 that Heck discloses that the lips (56) separate without excessive force being applied as a medical device passes through the lips. Again, this disclosure does not mean that the valve does not operate by compressing a catheter. Examiner asserts that the lips (56) separate to allow a medical device such as a catheter to be passed through it, but the catheter is nevertheless compressed by the lips (56) given the structure of the lips and given that a catheter has a lumen.

Appellant also argues on page 19, second and third full paragraph of the brief that claim 12 recites a valve sleeve seat that receives an end of the compressible valve sleeve. Appellant asserts that this claimed limitation does not allow the compressible valve sleeve to be inserted beyond the valve sleeve seat. Examiner asserts however that the limitation in claim 12 does not preclude the compressible valve sleeve from being inserted beyond the valve sleeve seat. For example, a proximal end (i.e., the end closest to the user) of the catheter can be received in the claimed valve sleeve seat, which is indicated as element (50) in the rejection.

Thus, Examiner asserts that Appellant has not provided limitations in the claims such that it differentiates the present invention from the Heck device.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

A.L.
September 29, 2004

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